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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/907,515	07/16/2001	Stephen J. Lippard	MTV-023.01	5698

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FOLEY HOAG LLP  
PATENT GROUP, WORLD TRADE CENTER WEST  
155 SEAPORT BOULEVARD  
BOSTON, MA 02110-2600

EXAMINER

BAKER, MAURIE GARCIA

ART UNIT

PAPER NUMBER

1627

DATE MAILED: 09/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. <b>09/907,515</b>	Applicant(s) <b>Lippard et al</b>
Examiner <b>Maurie G. Baker, Ph.D.</b>	Art Unit <b>1627</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ONE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on \_\_\_\_\_

2a)  This action is **FINAL**.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 835 C.D. 11; 453 O.G. 213.

4)  Claim(s) 1-32 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) \_\_\_\_\_ is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims 1-32 are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1)  Notice of References Cited (PTO-892)      4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)      5)  Notice of Informal Patent Application (PTO-152)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_      6)  Other: \_\_\_\_\_

## DETAILED ACTION

**Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1627 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

### *Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-14, drawn to a method of identifying one or more coordination complexes, classified in various classes and subclasses, for example, class 435, DIG 11.
  - II. Claims 15 and 16, drawn to a method for preparing a library, classified in various classes and subclasses depending on the exact structure of the library members made, for example, class 435, DIG 46.
  - III. Claims 17-23, drawn to a library, classified in various classes and subclasses depending on the exact structure of the library members, for example, class 435, DIG 29-31.
  - IV. Claims 24-28, drawn to a coordination complex and pharmaceutical compositions comprising the complex, classified in various classes and subclasses depending on the exact structure of the complex, for example, class 546, subclass 2.
  - V. Claim 29, drawn to a method of treatment, classified in various classes depending on the compound used, for example, class 514, subclasses 184+.
  - VI. Claim 30, drawn to a diagnostic tool, classified in various classes depending on the metal ion and complex structure, for example, class 424, subclasses 1.11+.

VII. Claims 31 and 32, drawn to a method of treating neoplasms, classified in various classes depending on the exact structure of the compound used, for example, any of classes 514 or 424, subclasses various.

2. The inventions are distinct, each from the other because of the following reasons:

3. Group III and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process. Specifically, the claimed library could be used as a starting material for synthesis of further libraries.

4. Group III and II are related as product and process of making. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the library of Group III could be made by other processes; for example, by solid phase synthesis techniques.

5. Groups III, IV & VI represent separate and distinct products. They differ in respect to their properties, their use and the synthetic methodology for making them.

Therefore, they have different issues regarding patentability and enablement and represent patentably distinct subject matter. In the instant case, the library of Group III is a composition comprising at least two members, while the products of Groups IV and VI represent distinct, single molecules. Libraries and single compounds also have different uses and require different methods of making. The coordination complex of Group IV is different from the diagnostic tool of Group VI as the metal ion would differ. Furthermore, these products also have different uses (therapeutic vs. diagnostic).

6. Groups I, II, V and VII are drawn to different methods. The methods are different because they use different steps, require different reagents and will produce different products and/or results. They therefore have different issues regarding patentability and enablement and represent patentably distinct subject matter. In the instant case, the method of identifying (Group I) and method of preparing (Group II) are completely different from the methods of treatment (Groups V and VII), requiring different reagents and having completely different end results.

7. Additionally, the method of identifying (Group I) and method of preparing (Group II) are different from each other because the steps of each method are different; i.e. the method of Group I requires assay and comparison steps not required by Group II and the method of Group II requires specific synthesis steps not required by Group I. Furthermore, the two methods of treatment (Groups V and VII) are different from each

other as the compounds used for the treatment are different. These methods also have different steps.

8. Therefore, the groups that describe these methods and products have different issues regarding patentability and enablement, and represent patentably distinct subject matter, which merits separate and burdensome searches. Art anticipating or rendering obvious each of the above-identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing features and/or characteristics. Each group could support a separate patent.

9. These inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. The different inventions would require different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

10. This application contains claims directed to patentably distinct species of the claimed invention for all of Groups I - VII. Election is required as follows.

11. If applicant elects the invention of **Group I**, applicant is required to elect from the following patentably distinct species. Please elect one species from *each* subgroup below. Claims 1 and 5 are generic.

IA. Species of coordination complex used in the method

Applicant is required to elect a coordination complex used in the method, for purposes of search. It is recognized that a library is made (i.e. step (a)); however, the following portions of the claimed library members must be defined:

- (1) specific metal ion; (2) general structural formula (e.g. claim 13) and
- (3) specific number of ligands

IB. Species of assay (e.g. claims 6-12)

Applicant is required to elect, for purposes of search, *a specific assay* used in step (c) of the method, for purposes of search. Applicant should select from the assays set forth in claims 7, 8 or 9\*\*

\*\*If the assay set forth in claim 9 is elected, then a single “structure-specific recognition protein” should be elected from those set forth in claims 10-12

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made and/or in their specific steps and elements needed for carrying them out. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

12. If applicant elects the invention of **Group II**, applicant is required to elect from the following patentably distinct species. Claim 15 is generic.

Species of coordination complex made by the method

Applicant is required to elect a coordination complex made by the method, for purposes of search. It is recognized that a library is made; however, the following portions of the claimed library members must be defined:

- (1) specific metal ion; (2) general structural formula and
- (3) specific number of ligands

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made and/or in their specific steps and elements

needed for carrying them out. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

13. If applicant elects the invention of **Group III**, applicant is required to elect from the following patentably distinct species. Claim 17 is generic.

Species of library members

Applicant is required to elect specifics for the library members, for purposes of search. It is recognized that a library (not single compound) is claimed; however, the following portions of the claimed library members must be defined:

- (1) specific number of ligands (i.e. n must be defined)
- (2) identity of L ligands (i.e. applicant must elect from the non-mutually exclusive L groups set forth in claims 18-21. If the L groups are different then each should be defined)

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

14. If applicant elects the invention of **Group IV**, applicant is required to elect from the following patentably distinct species. Claims 24 and 27 are generic.

Species of coordination complex

Applicant is required to elect, for purposes of search, *a single, specific chemical structure* of the claimed coordination complex. Note that the elected structure should have all atoms and bonds shown, i.e. be completely defined.

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

15. If applicant elects the invention of **Group V**, applicant is required to elect from the following patentably distinct species. Claim 29 is generic.

Species of coordination complex used in the method

Applicant is required to elect, for purposes of search, *a single, specific chemical structure* of the coordination complex that is used in the claimed method. Note that the elected structure should have all atoms and bonds shown, i.e. be completely defined.

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity, starting materials from which they are made and mode of action in the body. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

16. If applicant elects the invention of **Group VI**, applicant is required to elect from the following patentably distinct species. Claim 30 is generic.

Species of “diagnostic tool”

Applicant is required to elect, for purposes of search, *a single, specific chemical structure* that comprises the claimed “diagnostic tool”. Note that the elected structure should have all atoms and bonds shown, i.e. be completely defined.

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity, starting materials from which they are made and mode of action in the body. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

17. If applicant elects the invention of **Group VII**, applicant is required to elect from the following patentably distinct species. Please elect one species from *each* subgroup below. Claim 31 is generic.

VIIA. Species of coordination complex used in the method

Applicant is required to elect, for purposes of search, *a single, specific chemical structure* of the coordination complex that is used in the claimed method. Note

that the elected structure should have all atoms and bonds shown, i.e. be completely defined.

**VIIB. Species of protein**

Applicant is required to elect, for purposes of search, ***a single, specific "structure-specific recognition protein"*** used in the claimed method (e.g. claim 32).

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made and/or in their specific steps and elements needed for carrying them out. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

18. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.
19. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and ***a listing of all claims readable thereon***, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.
20. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

21. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

22. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

23. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

24. Applicant is also reminded that a 1 - month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (703) 308-0065. The examiner can normally be reached on Monday-Thursday from 9:00 to 6:30 and alternate Fridays.

26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D.  
September 20, 2002



MAURIE GARCIA BAKER, Ph.D.  
PATENT EXAMINER



# RESTRICTION ELECTION FACSIMILE TRANSMISSION

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